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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,185	04/10/2006	Peter Ellinghaus	Le A 36 823	5232
35969	7590	03/24/2009		
Barbara A. Shimci Director, Patents & Licensing Bayer HealthCare LLC - Pharmaceuticals 555 White Plains Road, Third Floor Tarrytown, NY 10591			EXAMINER RAMACHANDRAN, UMAMAHESWARI	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			03/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/565,185

Applicant(s)

ELLINGHAUS ET AL.

ExaminerUMAMAHESWARI
RAMACHANDRAN**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3, 5 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claims 1-3, 5 are pending.

Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1) Group I, claim 1 is directed to a method of treating or preventing cardiac arrhythmias, comprising administering to a patient a modulator of a potassium channels TWIK-1, TASK-1, GIRK-1, SK2 or PCN1.

2) Group II, claim 2 is a method for screening test compounds to identify modulators of the potassium channels TWIK-1, TASK-I, GIRK1, SK2 or PCN1 which are suitable for producing a medicament for the treatment and/or prophylaxis of cardiac dysrhythmias (arrhythmias), coronary heart disease or hypertension.

3) Group III, claim 3, is a pharmaceutical composition comprising a modulator or a plurality of modulators of the potassium channels TWIK-1, TASK-I, GIRK1, SK2 or PCN1 for the treatment and/or prophylaxis of cardiac dysrhythmias (arrhythmias), coronary heart disease or hypertension.

4) Group IV, claim 4 is a method of treating cardiac arrhythmias, coronary heart disease or hypertension, comprising administering to a patient a modulator of gene

products which are expressed in the human heart differentially between left atrium and left ventricle.

The inventions listed as Groups I – IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression “special technical features” is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any). Whether or not any particular technical feature makes a “contribution” over the prior art, and therefore constitutes a “special technical feature”, should be considered with respect to novelty and inventive step.

The common technical feature in all the groups in the instant application is a modulator of gene products for treating cardiac arrhythmias, coronary disease or hypertension. Curtis (US 20020028483) teaches potassium channel modulators such as

TWIK modulators, and also teach the use of such compounds in treating disorders such as cardiac arrhythmias.

Jansen et al. (US 6,194,447) teaches potassium channel blocking agents capable of selectively blockade of SK channels, e.g. SK1, SK2 and/or SK3 channels and further teach the compounds are useful in ischemic heart disease, arrhythmias, hypertension etc. Also sotalol (<http://en.wikipedia.org/wiki/Sotalol>) is a known potassium channel blocker.

As a result, no special technical features exist among the different groups because the inventions in Groups I-IV fail to make a contribution over the prior art with respect to novelty or inventive step. In conclusion, there is lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.1.43).

The application contains claims directed to more than one species of the generic invention. If applicant elects a group from Groups I-IV, applicant is further required to elect single disclosed species. If applicant elects Group I, applicant is further required to elect single disclosed species of the disorder (e.g hypertension) and also a species of a potassium channel modulator compound of TWIK-1, TASK-1. GIRK-1, SK2 or PCN1 modulator (one single compound, e.g a TWIK-1 blocking agent). If applicants' elect Group II, applicants are further required to elect a single type of potassium channel modulator (e.g TWIK-1). If applicants' elect Groups III applicants' are required to elect a

single species, that is a single modulator compound from one of the types of TWIK-1, TASK-1, GIRK-1, SK2 or PCN1 modulators. If applicants elect Group IV, applicants are further required to elect a species of the disorder (e.g hypertension) and a modulator (one single compound, e.g a TWIK-1 blocking agent or sotalol) of a gene product which are expressed in the human heart differentially between left atrium and left ventricle.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly

and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

A telephone call to the attorney is not required where 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since the examiner knows from past experience that written restriction is preferred, a telephone election was not made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617